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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SWITZER, JULIET CAROLINE	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,129	KAUHANEN ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *4-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group 1, claims 1-2 in the reply filed on 4/15/04 is acknowledged. Upon further reconsideration, groups 2 and 3, both containing claims 1 and 3 are rejoined to group 1. Claims 1-3 are examined herein.

Examiner's Note

2. In claim 1, the second line recites "said subject." There is improper antecedent basis for this limitation, though it is clear from reading the claim that applicant is referring to the person being diagnosed. The claim would be clearer, however, if amended to read "said person" rather than "said subject." No rejection under 112 2nd paragraph has been set forth because this is not an aggravated situation where the lack of antecedent basis makes the scope of the claim indeterminate.

Specification

3. The disclosure is objected to because of the following informalities: There are drawings in the specification at pages 10 and 11. These should be removed. See rule 1.58(a).

Appropriate correction is required.

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for diagnosing a person's susceptibility for having a risk for the development of alcoholism, said method comprising determining whether said subject has a polymorphism in the signal pepetide part of the human preproNPY, said polymorphism comprising a substitution of proline for leucine at position 7 in the signal peptide part of said human preproNPY, said polymorphism being indicative of a risk for the development, wherein said polymorphism is detected in the nucleic acid sequence of said subject, does not reasonably provide enablement for methods which detect the polymorphism change via the use of a specific antibody or other polypeptide analysis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of the invention

The invention is drawn to a method for diagnosing a susceptibility for developing alcoholism which requires the detection of a polymorphism in the signal peptide part of the

human preproNPY. Thus, the nature of the invention is dependent upon the ability to detect the polymorphism itself.

Breadth of the Claims

The independent claim encompasses the detection of the polymorphism via any means. Claim 3 specifically recites that the polymorphism is detected utilizing an antibody capable of binding the signal peptide part of the human preproNPY or a NPY peptide associated with any other cleavage product of said human preproNPY.

Teachings of the Specification and Working Examples

The specification teaches and exemplifies the detection of the polymorphism within a nucleic acid sequence.

The specification teaches that the determination can be carried out as an immunoassay where a sample is contacted with an antibody capable of binding the signal peptide or a peptide associated with any other cleavage product of preproNPY (p. 6, lines 18-20). The specification does not teach any "other cleavage products of preproNPY." The specification generically teaches that antibodies can be raised against normal or mutated preproNPY utilizing in vivo or in vitro procedures. The specification does not exemplify such methods. Furthermore, the specification does not exemplify any additional methods by which a polymorphism in a polypeptide itself can be detected. The specification does not teach isolation of the polypeptide from any biological sample from a patient or how to identify the polypeptide in a sample for assay for the polymorphism.

State of the Art and Level of Unpredictability

The prior art teaches the detection of the polymorphism at position 7 in the signal peptide via analysis of nucleic acid sequence (see, for example, Okubu *et al.* as cited in the IDS). The prior art does not teach isolation and/or detection of the polymorphism via an antibody that differentiates the two alleles or via any other method. Neither the specification nor the prior art appear to provide the binding epitopes for the human preproNPY, and it is unclear whether the amino acid change in the seventh position of the signal sequence would be sufficient to result in the production of antibodies that can differentiate between the two molecules. In some cases, an antibody elicited by one antigen can cross-react with a different antigen if the two different antigens share an identical or very similar epitope (Glodsby *et al.*, 2003, p. 141). In the instant case, it is unpredictable as to whether or not an antibody would be able to differentiate between the two variants, a feature that is essential for the practice of the claimed invention.

Conclusion

Thus, having considered these factors, particularly the absence of working examples, teaching in the specification and prior art, and high degree of unpredictability, it is concluded that it would require undue experimentation to practice the invention of claim 1 commensurate in scope with the claimed invention and it would also require undue experimentation to practice the invention of claim 3.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 3 recites the limitation "said NPY pepetide associated with any other cleavage product " in line 4. There is insufficient antecedent basis for this limitation in the claim because the claim does not previously recite an NPY pepetide. It is not clear which peptide is being referred to as "said NPY pepetide associated with any other cleavage product" as the claims do not appear to previously mention such a peptide.

Allowable Subject Matter

11. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached by calling (571) 272-0782.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Juliet C. Switzer
Examiner
Art Unit 1634

July 9, 2004